

Transcutaneous Inserter (Attorney Docket No. 1062/E74), which is hereby incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0026] This application relates generally to fluid delivery systems, and more particularly to infusion pump assemblies.

BACKGROUND

[0027] Many potentially valuable medicines or compounds, including biologicals, are not orally active due to poor absorption, hepatic metabolism or other pharmacokinetic factors. Additionally, some therapeutic compounds, although they can be orally absorbed, are sometimes required to be administered so often it is difficult for a patient to maintain the desired schedule. In these cases, parenteral delivery is often employed or could be employed.

[0028] Effective parenteral routes of drug delivery, as well as other fluids and compounds, such as subcutaneous injection, intramuscular injection, and intravenous (IV) administration include puncture of the skin with a needle or stylet. Insulin is an example of a therapeutic fluid that is self-injected by millions of diabetic patients. Users of parenterally delivered drugs may benefit from a wearable device that would automatically deliver needed drugs/compounds over a period of time.

[0029] To this end, there have been efforts to design portable and wearable devices for the controlled release of therapeutics. Such devices are known to have a reservoir such as a cartridge, syringe, or bag, and to be electronically controlled. These devices suffer from a number of drawbacks including the malfunction rate. Reducing the size, weight and cost of these devices is also an ongoing challenge. Additionally, these devices often apply to the skin and pose the challenge of frequent re-location for application.

SUMMARY OF THE INVENTION

[0030] According to a first implementation, a wearable infusion pump assembly includes a reservoir for receiving an infusible fluid, and an external infusion set configured to deliver the infusible fluid to a user. A fluid delivery system is configured to deliver the infusible fluid from the reservoir to the external infusion set. The fluid delivery system includes a volume sensor assembly, and a pump assembly for extracting a quantity of infusible fluid from the reservoir and providing the quantity of infusible fluid to the volume sensor assembly. The volume sensor assembly is configured to determine the volume of at least a portion of the quantity of fluid. The fluid delivery system also includes at least one optical sensor assembly, a first valve assembly configured to selectively isolate the pump assembly from the reservoir. The fluid delivery system further includes a second valve assembly configured to selectively isolate the volume sensor assembly from the external infusion set. The at least one optical sensor assembly is configured to sense the movement of the pump assembly.

[0031] One or more of the following features may be included. The wearable infusion pump may also include a second optical sensor assembly configured to sense the movement of the second valve assembly. The wearable infusion pump assembly may also include a disposable housing assembly including the reservoir and a first portion of the fluid delivery system. The wearable infusion pump

assembly may also include a reusable housing assembly including a second portion of the fluid delivery system. A first portion of the pump assembly may be positioned within the disposable housing assembly. A second portion of the pump assembly may be positioned within the reusable housing assembly. A first portion of the first valve assembly may be positioned within the disposable housing assembly. A second portion of the first valve assembly may be positioned within the reusable housing assembly. A first portion of the second valve assembly may be positioned within the disposable housing assembly. A second portion of the second valve assembly may be positioned within the reusable housing assembly. The at least one optical sensor may be positioned within the reusable housing assembly.

[0032] The external infusion set may be a detachable external infusion set that may be configured to releasably engage the fluid delivery system.

[0033] The wearable infusion pump assembly may include at least one processor, and a computer readable medium coupled to the at least one processor. The computer readable medium may include a plurality of instructions stored on it. When executed by the at least one processor, the instructions may cause the at least one processor to perform operations including activating the first valve assembly to isolate the pump assembly from the reservoir. The computer readable medium may also include instructions for activating the pump assembly to provide the quantity of infusible fluid to the volume sensor assembly.

[0034] The fluid delivery system may include an actuator associated with the first valve assembly. Activating the first valve assembly may include energizing the actuator. The actuator may include a shape memory actuator. The fluid delivery system may include an actuator associated with the pump assembly.

[0035] Activating the pump assembly may include energizing the actuator. The fluid delivery system may include a bell crank assembly for mechanically coupling the pump assembly to the actuator. The actuator may include a shape memory actuator.

[0036] The computer readable medium may further include instructions for activating the volume sensor assembly to determine the volume of at least a portion of the quantity of fluid provided to the volume sensor assembly from the pump assembly. The computer readable medium may also include instructions for activating the second valve assembly to fluidly couple the volume sensor assembly to the external infusion set.

[0037] The fluid delivery system may include an actuator associated with the second valve assembly and activating the second valve assembly includes energizing the actuator. The fluid delivery system may include a bell crank assembly for mechanically coupling the second valve assembly to the actuator. The actuator may include a shape memory actuator.

[0038] The fluid delivery system may further include a bracket assembly that may be configured to maintain the second valve assembly in an activated state. The computer readable medium may further include instructions for activating the bracket assembly to release the second valve assembly from the activated state. Activating the bracket assembly may include energizing a bracket actuator associated with the bracket assembly. The bracket actuator may include a shape memory actuator.

[0039] The details of one or more embodiments are set forth in the accompanying drawings and the description